IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

MUTUAL PHARMACEUTICAL COMPANY, INC. Plaintiff, v. HOECHST MARION ROUSSEL, INC., Defendant.	:	CIVIL ACTION No. 96-1409
HOECHST MARION ROUSSEL, INC., and MERRELL PHARMACEUTICALS INC. Counterclaim-plaintiffs, v. MUTUAL PHARMACEUTICAL CO., INC, Counterclaim-defendant.	:	
MUTUAL PHARMACEUTICAL CO., INC., Counterclaim-plaintiffs, v. HOECHST MARION ROUSSEL, INC., and MERRELL PHARMACEUTICALS INC., Counterclaim-defendants.	:	

MEMORANDUM-ORDER

GREEN, S.J. **December , 1997**

Presently pending is Defendant's Motion for Summary Judgment and Plaintiff's Response thereto. For the reasons set forth below, Defendant's Motion will be denied.

FACTUAL AND PROCEDURAL BACKGROUND

Plaintiff Mutual Pharmaceutical Company, Inc. ("Mutual") filed suit against Defendant Hoechst Marion Roussel, Inc. ("HMR") alleging that HMR unlawfully monopolized, or attempted to monopolize, the market for terfenadine. HMR holds a patent for, and until recently was the exclusive FDA-approved producer of, terfenadine, more commonly known and marketed by HMR as the non-

sedating antihistamine product Seldane®.[1] Mutual had an Abbreviated New Drug Application ("ANDA") pending before the Food & Drug Administration ("FDA") in order to produce a generic version of terfenadine. Prior to filing its ANDA, Mutual relied upon the patents listed in the Orange Book to determine if filing the ANDA would violate any existing patents for terfenadine.[2] As of July 2, 1993, the date Mutual filed its ANDA for terfenadine, the only patent listed in the Orange Book for terfenadine was HMR's patent number 3,878,217 ("'217 patent"). HMR's patent number 4,254,129 ("'129 patent") for terfenadine was not listed. Mutual allegedly determined from the July 1993 Orange Book listing that it was only required to make a certification with respect to HMR's '217 patent.[3] Mutual filed a paragraph III

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1. Seldane® and terfenadine will be used interchangeably throughout this memorandum.

2. The Orange Book, published by the Secretary of Health and Human Services, lists each drug, accompanied by its patent number, which has been approved for safety and effectiveness.

3. An applicant submitting an ANDA to the FDA must certify that either: (1) such patent information has not been filed by the patentee; (2) the existing patent has expired; (3) the date on which the existing patent will expire ("a paragraph III Certification"); or, (4) the existing patent is invalid, or that it will not be infringed by the manufacture, use or sale of the new drug for which the ANDA is submitted ("a paragraph IV Certification"). 21 U.S.C. § 355(j)(2)(A)(vii). If an ANDA contains a paragraph IV Certification and all other requirements have been met, approval of the ANDA is effective immediately unless the patent owner brings an action for infringement under 35 U.S.C. § 271 (e)(2). 21 U.S.C. § 355(j)(4)(B)(iii). Including a paragraph IV Certification in an ANDA, however, is deemed an act of infringement, and when a patent owner brings an infringement action, the FDA must suspend approval of the ANDA for a maximum of thirty (30) months or until the court renders a decision. Id.; 35 U.S.C. § 271(e)(2)(A).

Certification for the '217 patent which was to expire on April 15, 1994. Mutual did not, however, file any certification for the '129 patent because HMR's '129 patent had not been listed in the Orange Book for more than seven years prior to the date Mutual filed its ANDA.

In September of 1993, HMR re-listed its '129 patent for terfenadine in the Orange Book. The FDA concluded that Mutual was not required to make any certification regarding HMR's '129 patent because HMR failed to file the patent information in a timely manner. HMR (formerly Marion Merrell Dow, Inc.) sued the FDA in Marion Merrell Dow, Inc. v. Kessler, et al., No. 94-1708-RCL (D.C. 1995). The D.C. district court granted summary judgment, holding that the '129 patent was timely listed and that the FDA could not issue final approval for any ANDA for terfenadine if the ANDA failed to contain either a paragraph III or IV Certification for the '129 patent.[4] As a result of the court's decision, the FDA was precluded from approving Mutual's ANDA for terfenadine.

Mutual alleges that HMR willfully manipulated the FDA registration process and failed to list the '129 patent in the Orange Book in a timely manner. Mutual asserts that the purpose

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4. The FDA has appealed the district court order in Marion Merrell Dow, Inc. v. Kessler, et al., No. 94-1708-RCL (D.C. 1995). Based on the district court's finding that the '129 patent was timely listed, that finding alone, if affirmed, may preclude plaintiff from succeeding on a claim based on an alleged manipulation of the orange book listing. The appeal has been stayed pending FDA action on an FDA Notice of its intention to withdraw its approval of Seldane®.

and effect of HMR's failure to list the '129 patent in a timely manner was to: (1) increase the restraint on competition in the sales of terfenadine; (2) unreasonably foreclose the market for terfenadine to competitors; (3) facilitate a monopoly position in terfenadine; and, (4) decrease competition in violation of the Sherman Act. (Pl.'s Compl. ¶ 91.) Mutual further maintains that HMR relisted the '129 patent for the express purpose of monopolizing or attempting to monopolize the terfenadine market to prevent Mutual from obtaining approval of its ANDA for terfenadine. (Pl.'s Compl. ¶ 92.)

HMR filed its motion for summary judgment on the issue of relevant market definition. Mutual has pled a relevant market of terfenadine. HMR claims that Mutual has failed to define a relevant market because terfenadine competes vigorously with other non-sedating antihistamines. Mutual admits that terfenadine competes with other non-sedating antihistamines for some consumers, however, Mutual contends that it has not alleged monopoly power in HMR as to the broader market of non-sedating anthistamines. Rather, Mutual has only alleged a relevant market of terfenadine based on consumers for whom only terfenadine provides therapeutic relief.

The evidence presented by both parties establishes that terfenadine, distributed as Seldane®, and loratadine, distributed as Claritin®: (1) treat the same or similar symptoms; (2) function via histamine inhibitors; (3) are priced similarly; (4) are aggressively marketed and promoted against one another; and,

(5) largely compete for the same customers. (Rozek Dec. at ¶¶ 13, 35; Meltzer Dec. at ¶¶ 19-24; Parks Dec. at ¶9; see also Hamaty Dec. ¶¶ 2-4, 28; Kursh Dec. at ¶4; Bolton Dec. at ¶¶ 10-11.) Mutual states that it "does not dispute that a broader general market exists for non-sedating antihistamines and that in that broad market there are consumers for whom Claritin® and other non-sedating antihistamines may prove entirely satisfactory substitutes for terfenadine." (Pl.'s Reply Memorandum at 29.)

The evidence also shows that terfenadine and loratadine are completely distinct drugs with different chemical structures and efficacy in treating people. (See Hamaty Dec., ¶¶ 28-29; Bolton Dec. at ¶¶ 2-5, 11.) Mutual has submitted declarations of both a physician and pharmacologist supporting its assertion that for some non-sedating antihistamine product consumers, it is possible that either loratadine or terfenadine is effective, but not both. (See Hamaty Dec., ¶¶ 28-29; Bolton Dec. at ¶¶ 2-5, 11.) Furthermore, the FDA recognized terfenadine as a unique product by permitting Seldane® to stay on the market prior to the introduction of Allegra® despite its accompanying cardiac risks because of terfenadine's distinct qualities and effectiveness.[5]

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5. Prior to Allegra's® introduction into the antihistamine market, terfenadine was the only chemical combination which, when metabolized by the liver, produced the compound TAM. Terfenadine, however, had serious adverse effects when combined with any of a number of widely prescribed drugs. In 1996, HMR introduced Allegra®, another TAM based non-sedating drug. Allegra's® active chemical compound is fexofenadine, which is not accompanied by the adverse effects of terfenadine. Consequently, the FDA has proposed removal of terfenadine from the market. (It should be noted that loratadine, or Claritin®, is not a TAM based

(FDA Talk Paper, July 13, 1997; FDA Notice, 9-11, Exs. "A" and "E" to Langer Dec.). The FDA Notice and Talk Paper state that terfenadine's benefits outweighed its risks and that because it provided a unique therapeutic benefit to some consumers, it should stay on the market. (See Exs. "A" and "E" to Langer Dec.)

DISCUSSION

Summary judgment shall be awarded "if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c). Summary judgment will be inappropriate where a dispute regarding a material fact is genuine, that is, if the evidence is such that a reasonable jury could return a verdict for the non-moving party. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248, 106 S. Ct. 2505, 2510 (1986). The evidence presented must be viewed in the light most favorable to the non-moving party. Lang v. New York Life Ins. Co., 721 F.2d 118, 119 (3d Cir. 1983). The moving party has the initial burden of demonstrating that no genuine issue of material fact exists. See Celotex Corp. v. Catrett, 477 U.S. 317, 323, 106 S. Ct. 2548, 2553 (1986).

To succeed on its monopolization claim, Mutual must demonstrate that HMR: (1) possessed monopoly power in the relevant market and (2) willfully acquired or maintained that

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product).

power as distinguished from growth or development as a consequence of a superior product, business acumen, or historic accident. U.S. v. Grinnell Corp., 384 U.S. 563, 570-1, 86 S. Ct. 1698, 1704 (1966). To succeed on its attempted monopolization claim, Mutual must prove: "(1) that [HMR] has engaged in predatory or anticompetitive conduct with (2) a specific intent to monopolize and (3) a dangerous probability of achieving monopoly power." Spectrum Sports, Inc. v. McQuillan, 506 U.S. 447, 456, 113 S. Ct. 884, 890-91 (1993). Plaintiff bears the burden of defining the relevant market and demonstrating that such a market exists. See Pastore v. Bell Tel. Co. of Pa., 24 F.3d 508, 512 (3d Cir. 1994).

The "market" which one must study to determine when a producer has monopoly power is composed of products that have reasonable interchangeability for the purposes for which they are produced -- price, use and qualities considered. United States v. E.I. duPont de Nemours and Co., 351 U.S. 377, 404, 76 S. Ct. 994, 1012 (1956). "Defining a relevant market is a process of describing those groups of producers which, because of similarity of their products, have the ability -- actual or apparent -- to take significant amounts of business away from each other. Smithkline Corp. v. Eli Lilly and Co., 575 F.2d 1056, 1063 (3d Cir.), cert. denied, 439 U.S. 838, 99 S. Ct. 123 (1978).

The Supreme Court has held that in some instances a single brand of a product may constitute a relevant market or a separate submarket. Eastman Kodak v. Image Technical Svcs., 504 U.S. 451,

481-82, 112 S. Ct. 2072, 2090 (1992)(citations omitted). In Kodak, the Court found that the proper market definition for antitrust purposes is determined by the choices available to the ultimate consumer and could only be determined after a factual inquiry into the 'commercial realities' faced by the consumers." Id.

In the present case, Mutual has provided evidence which establishes that terfenadine is a unique chemical compound with particular effectiveness and possibly a distinct set of consumer users. Despite HMR's evidence that Claritin® is a direct competitor of Seldane®, Mutual's evidence raises a genuine issue of material fact as to whether a relevant market for terfenadine exists based on consumers for whom only terfenadine provides therapeutic relief. Whether a relevant market for terfenadine exists can only be decided on a full record at trial. Accordingly, summary judgment on the issue of relevant market is denied.

An appropriate Order follows.